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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/797,946	03/11/2004	David B. Wiley	632898-042-C1	4846

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EXAMINER

GEMBEH, SHIRLEY V

ART UNIT	PAPER NUMBER
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1614

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/19/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/797,946

Applicant(s)

WILEY ET AL.

Examiner

Shirley V. Gembeh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 October 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The response filed **October 9, 2006** presents remarks and arguments to the office action mailed **April 19, 2006**. Applicants' request for reconsideration of the rejection of claims in the last office action has been considered.

Applicants' arguments, filed, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Status of Claims:

Claims 1-25 are pending.

Claims 1 and 12 have been amended.

Maintained Claim Rejections - 35 USC § 112-2

Applicant argues that the about is a descriptive term and is commonly used, citing Ecolab Inc v. Envirochem, Inc. (see page 6 of remarks, para. 4).

In response, the term about permits some tolerance, but the term from about does not provide a standard for asserting a requisite degree. Where does "from" start? Applicant's arguments have been fully considered but they are not persuasive. See reasons above and the rejection is maintained as in the last office action of record.

Claims 2, 4, 6, 8, 12, 13, 15, 17, 18, 21, 22 and 24 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "from about" in claims 2, 4, 6, 8, 12, 13, 15, 17, 18, 21, 22 and 24 is a relative term which renders the claim indefinite. The term "from about" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Because one of skill will not be able to determine which term is in control.

Maintained *Claim Rejections* - 35 USC § 112

Claims 1-11 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for decreasing serum level of triglycerides in mammals, does not reasonably provide enablement for preventing condition associated with calcium and or magnesium deficiency. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Applicant in part addressed the 112-1 enablement rejection, but however failed to address the conditions associated with calcium and or magnesium because there are a wide variation condition associated with calcium and or magnesium. A listing of a few of these conditions are treatment of diabetic retinopathy, chronic venous insufficiency,

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haemorrhoids, sudden death in familial polymorphic ventricular tachycardia, agranulocytosis, hyperglycemia, renal stone or kidney stones and a lot more conditions, which is not enabled or has not shown how one of skill is able to alleviate the pathological effects of calcium or magnesium deficiency, comprising administering the instant compound to a patient (human) in need thereof. As stated, however, claim 1 includes within its scope, any calcium or magnesium deficiency condition or disease or at most a wide variation of conditions.

Applicant's arguments have been fully considered but they are not persuasive.

See reasons above and the rejection is maintained as in the last office action of record

Claims 1-11 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for decreasing serum level of triglycerides in mammals, does not reasonably provide enablement for preventing condition associated with calcium and or magnesium deficiency. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Maintained Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

- I. Claims 1, 3, 5-6, 9, 11-12 and 14 remain rejected under 35 U.S.C. 102(b) as being anticipated by Nissen et al. US 6,031,000.

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Applicant argues that the above cited reference the “present invention independent claims 1 and 12 of the present application recite treating a subject having a condition associated with calcium and/or magnesium deficiency and treating a subject in need of a nutritionally supplemental amount of calcium and/or magnesium and said mineral supplement is administered in an amount sufficient to supply said nutritionally supplemental amount, respectively” and that these limitations are not taught by the reference.

In response, Applicants’ remark is found unpersuasive because, the reference does teach a nutritional supplement (se col. 6, lines 55-58) as a food stuff- and also teaches that the calcium 3-hydroxy-3-methylbutyrate (HMB) salt can be added to nutritional IV solutions (see col. 7, lines -19) in the treatment of AIDS patient. Please note the condition associated with calcium and or magnesium is broad and has been applied here.

Applicant's arguments have been fully considered but they are not persuasive. See reasons above and the rejection is maintained as in the last office action of record

II. Claims 1, 5-6 and 9 remain rejected under 35 U.S.C. 102(b) as being anticipated by Vukovich et al. American Soc. Nutr. Sci.

Applicant argues that the reference fails to teach the claim invention treating a condition associated with calcium and or magnesium as recited in the instant claim 1. In response, Applicant has not define what these conditions are. The claim as it recites is capable of treating any condition associated with calcium and or magnesium.

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Examiner asserts that increasing gain in strength and fat-free mass during resistant exercise is a condition.

With regards to the nutritional supplement, on page 2049 underlined sec. of the reference (of record) administers 10 day supply of supplement, and nutrition supplement can be in the form of a tablet, food, liquid. Also please note that dietary or nutritional supplement are giving to supply nutrients in the form of vitamins, minerals, fatty acid or amino-acid that are missing in the patients diet.

Applicant's arguments have been fully considered but they are not persuasive. See reasons above and the rejection is maintained as in the last office action of record

III. Claims 1, 5-6, 7-9, 12 remain rejected under 35 U.S.C. 102(b) as being anticipated by WO 94/17678.

Applicant applies the same arguments to the above rejection, that the reference fails to teach the claim invention treating a condition associated with calcium and or magnesium as recited in the instant claims 1.

In response, the abstract clearly teaches enhancing the nutritional value of colostrum and first milk of a pregnant woman. Again Examiner has shown that the same compound as claimed is administered to pregnant mammals because bone loss occurs during pregnancy and during lactation, thus anticipated a condition associated with calcium and or magnesium.

Applicant's arguments have been fully considered but they are not persuasive. See reasons above and the rejection is maintained as in the last office action of record

Claim Rejections - 35 USC § 103

Applicant argues that the references fail to show motivation to one of ordinary skill in the art to make modifications (see page 8 bridging 9 of remarks).

In response, one of ordinary skill in the art would have been motivated to combine the cited art because the cited art teach a condition associated with calcium and or magnesium. Nothing unobvious is seen to combine the cited art to treat a condition associated with calcium and/or magnesium to treat a bone loss disease or a fat free –mass in resistance training. A condition associated with calcium and magnesium is any condition and Examiner has applied the conditions associated with calcium and or magnesium, which is within the claim limitation.

Applicant also argues that claim13 require both calcium and magnesium present, this is incorrect as claim 13 depends from claim 12 which clearly has the limitation and/or.

The naturalconnections.com cures is accurately applied as it states the ration of calcium and magnesium in the instant claims 12, 13 and 21.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, both magnesium

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and calcium have been used to treat a condition associated with calcium and/or magnesium condition because both elements share left / right-sided cell receptors and are essential to human health. Calcium (Ca) and magnesium (Mg) have become the "Gold Standard" when discussing supplements, mineral ratios, paired cell receptors, or many nutrition-related health issues in general.

Applicant's arguments have been fully considered but they are not persuasive. See reasons above and the rejection is maintained as in the last office action of record

Claims 1-25 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Nissen et al. US 6,031,000 taken with Vukovich et al. American Soc. Nutr. Sci. and WO 94/17678 in view of www.naturalconnections.com (1998).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 - 25 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6, 12-20, 26-33 and 37-39 of U.S. Patent Application No. **10667283**. Although the conflicting claims are not identical, they are not patentably distinct from each other. The reasons are as follows:

Both sets of claims refer to treating a condition associated with calcium and /or magnesium- in the current application (claims 1 - 25) and elevating blood serum levels (claims 1-6, 12-20, 26-33 and 37-39) in the copending application. The current application claims anticipate the copending application claims

Both applications recite using the same compositions and/or derivatives thereof. See current application claims 1 - 25 and copending application claims 1-6, 12-20, 26-33 and 37-39. The compositions recited in the claims are anticipatory of each other.

In view of the foregoing, the copending application claims and the current application claims are obvious variations.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shirley V. Gembeh whose telephone number is 571-272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SVG
01/2/07


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SUPERVISORY PATENT EXAMINER